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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,148	02/26/2004	Shiu-Ru Lin	BHT/3230-85	8192

7590 01/23/2008
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EXAMINER
WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
01/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,148

Applicant(s)

LIN ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 1,3 and 5-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 1-79 are pending in the application.

Claims 1, 3 and 5-79 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Claims 2 and 4 are under examination.

Withdrawn Objection/Rejection

In view of the amendments to the claims the objection to claim 4 and 35 USC 112 rejection are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 1 is indefinite. The phrase "gene sequences are selected from the group consisting of" is unclear as there is

only one sequence claimed (the other sequences had been cancelled).

2. Claim 4 is unclear in the recitation of gene sequencess. Claim 1 from which it depends recites only one sequence, ID. 5.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 4, as amended, are rejected under 35

U.S.C. 102(e) as anticipated by or, in the alternative, under 35

U.S.C. 103(a) as obvious over Bertucci et al(20050287544).

Bertucci et al discloses in the abstract:

Differential gene expression associated with histopathologic features of colorectal disease can be performed with nucleic acid arrays. Such arrays can comprise a pool of polynucleotide sequences from colon tissues, and the detection of the overexpression or underexpression of polynucleotide sequences (or subsequences or complements thereof) from this pool can provide information relating to the detection, diagnosis, stage, classification, monitoring, prediction, prevention or treatment of colorectal disease.

Bertucci et al discloses at paragraph:

[0009] DNA microarrays(biochip, as claimed) may be utilized to elucidate discrete gene sets to improve the prognostic classification of CRC, identify novel potential therapeutic targets of carcinogenesis, describe new diagnostic and/or prognostic markers, and guide physician decisions on appropriate patient care.

[0010] The invention thus provides a method for analyzing differential gene expression associated with histopathologic features of colorectal disease, comprising the detection of the overexpression or underexpression of a pool of polynucleotide sequences in colon tissues, said pool comprising all or part of the polynucleotide sequences, subsequences or complements thereof, selected from each of predefined polynucleotide sequence sets I through 644 set forth in Table 1.

[0011]The pool of polynucleotide sequences comprises all or part of the polynucleotide sequences, subsequences or complements thereof, selected from each of predefined polynucleotide sequence sets 1 through 644, as set forth in Table 1.

[0012] The invention further provides a polynucleotide library, comprising a pool of polynucleotide sequences either overexpressed or underexpressed in colon tissue, said pool corresponding to all or part of the polynucleotide sequences of **SEQ ID Nos. 1 through 1596**.

See further the Examples and claims.

Claims 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Eveleigh et al (20040146921).

[0002] The present invention relates to gene expression profiles for colon cancer, microarrays (biochip, as in claim 4) comprising nucleic acid sequences representing gene expression profiles, and methods of using expression profiles and microarrays.

[0042] The terms "array" or "matrix" refer to an arrangement of addressable locations or "addresses" on a device. The locations can be arranged in two-dimensional arrays, three-dimensional arrays, or other matrix formats. The number of locations may range from several to at least hundreds of thousands. Most importantly, each location represents a totally independent reaction site. A "nucleic acid array" refers to an array containing nucleic acid probes, such as oligonucleotides or larger portions of genes. The nucleic acid on the array may be single-stranded. Arrays wherein the probes are oligonucleotides are referred to as "oligonucleotide arrays" or "oligonucleotide chips." A "microarray," also referred to herein as a "biochip" or "biological chip," is an array of regions having a density of discrete regions of, for example, at least about 100/cm², or at least about 1000/cm². The regions in a microarray have typical dimensions, for example, diameters, in the range of between about 10-250 μ m, and are separated from other regions in the array by about the same distance.

[0055] Tumors of the digestive tract include, but are not limited to, anal, colon, colorectal, esophageal, gallbladder, gastric, pancreatic, rectal, small-intestine, and salivary gland cancers.

See further the sequences of genes, Seq. ID. 1-191.

Claims 2 and 4, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al (WO 00155351).

Rosen discloses in the claims and sequences a gene that is used for diagnosing colorectal cancer. See also page 5, line 15 up to page 6, line 17. The colon cancer antigen with Sequence X is disclosed at page 8, lines 14-31. See also Table 1 as to the different gene sequences. Rosen at page 220, line 27 up to page 221, line 27 discloses a solid support(biochip, as claimed) to which the gene antigen is attached thereto.

Response to Arguments

Applicants state that the Office believed claim 2 did not positively recite any gene sequence. Claim 2 has been amended to now positively recite Seq. ID. No. 5 (the elected species). These rejections are now believed to be moot.

In reply each of the references above discloses the claimed Seq. ID. NO. 5. For example, Bertucci recites Seq. ID. 1-1596 with the same function as claimed i.e., for diagnosing colorectal cancer. Hence, the claimed sequence on an array is fully met by Bertucci. Even assuming, Bertucci does not disclose the claimed sequence, which however he does, the claimed sequence would be a property inherent to the genes expressed on colon cancer.

Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); *In re Best* 195 USPQ 430 (CCPA 1977).

Since applicants' arguments are directed to same with the other cited references i.e., *Eveleigh* and *Rosen* hence, the responses above also apply to these references.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

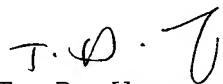
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
January 16, 2007